REMARKS

The claims are 22-37 and claims 22 and 30 are independent claims. Claims 1-21 have been cancelled without prejudice or disclaimer. Support for the amendments to claim 22 and claim 30 may be found in the specification on page 4, line 27. Claims 23-29 and 31-37 have been amended to make formal changes. No new matter has been added.

Claims 22-37 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pool et al. (US Patent No. 5,741,803, hereafter '803). Applicants respectfully traverse this rejection.

The Examiner contends that it would have been obvious to one of ordinary skill in the art in possession of the compound of '803, to adapt the compound to the sustained release composition providing the particular plasma concentration as claimed by Applicants. Applicants respectfully disagree and submit that although '803 discloses that a unit dose of 0.1-1000 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione may be administered 1-6 times a day, '803 does not disclose or suggest a pharmaceutical composition of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione that releases 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione at a rate that achieves a specified plasma concentration over a specified period of time, as set out in the pending claims.

It is well settled that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify a reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicants respectfully submit that '803 fails to support a *prima facie* case of obviousness in this case because '803 fails to:

a) disclose or suggest a sustained release pharmaceutical composition of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione;

b) disclose or suggest a sustained release pharmaceutical composition that provides any specific plasma concentration of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione;

c) disclose or suggest a sustained release pharmaceutical composition that provides a threshold plasma concentration of 50 ng/mL of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or provide any motivation to prepare a sustained release pharmaceutical composition that provides a threshold plasma concentration of 50 ng/mL of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione;

d) disclose or suggest a sustained release pharmaceutical composition that maintains a specified plasma concentration of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for any specific period of time;

e) disclose or suggest a sustained release pharmaceutical composition that maintains a plasma concentration of at least 50 ng/mL of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for any specific period of time;

f) disclose or suggest a sustained release pharmaceutical composition that maintains a plasma concentration of at least 50 ng/mL of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for a period of 12 hours or provide any motivation to prepare a sustained release pharmaceutical composition that maintains a plasma concentration of at least 50 ng/mL of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione for 12 hours.

Accordingly, Applicants respectfully submit that the subject claimed invention is patentable over the disclosure of '803.

Applicants believe that that the subject application is in condition for allowance. If the Examiner has any objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned agent to resolve such issues and advance the case to issue.

This Amendment is being filed together with a Request for Continued Examination. Applicants hereby petition for a 1-month extension of time for response from the date of the Examiner's action. In the event that these papers get separated, or there is any deficiency in the Petition, this constitutes a Petition for Extension of Time for the minimum period required to effect timely filing and consideration of this Amendment and Information Disclosure Statement, together with authorization to charge any fees under 37 C.F.R. §1.16 or §1.17 which may be required by these papers to Deposit Account No. 19-2570.

Respectfully submitted,

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